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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/011,167 10/05/98 GEUZE J RILE.001.000

HM22/0504

EXAMINER

BARBARA RAE VENTER
RAE VENTER LAW GROUP
PO BOX 60039
PALO ALTO CA 94306-0039

DECLLOUX, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1644

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DATE MAILED:

05/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------|--------------------------------------|-----------------------------------------|
| Advisory Action | Application No. 09/011,167 | Applicant(s) Gueze And Melief |
| | Examiner DeCloux, Amy | Art Unit 1644 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED mailed 4-17-01 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) The period for reply expires 3 months from the mailing date of the final rejection.

b) In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. A Notice of Appeal was filed on _____ . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. The proposed amendment(s) will not be entered because:
 - (a) they raise new issues that would require further consideration and/or search. (See NOTE below);
 - (b) they raise the issue of new matter. (See NOTE below);
 - (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: Newly added claim 14 raises new issues which require further consideration and search. See attached sheet.

4. Applicant's reply ~~has~~ ^{would} overcome the following rejection(s):
The 112 1st written description, the 102, and the 112 2nd paragraph rejections, and the objection to the specification.
However, the 112 1st enablement rejection would be maintained. See attached sheet.

5. Newly proposed or amended claim(s) _____ would be allowable if submitted in separate, timely filed amendment cancelling the non-allowable claim(s).

6. The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because:

7. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 2-4, 6, and 13

9. The proposed drawing correction filed on _____ a) has b) has not been approved by the Examiner.

10. Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. Other: _____

DETAILED ACTION

1. Applicant's after-amendment, mailed 4-17-01 (Paper No. 17) is acknowledged, but has not been entered because newly added claim 14 raises new issues by adding the limitation that the claimed vesicle does not contain a transferrin receptor, and thus requires further consideration and search. Therefore, the after-final amendment has not been entered.
2. Though applicant's arguments and amendments in their after-final amendment mailed 10-27-00 (Paper No. 15), have been carefully considered, the 112 first rejection is maintained essentially for the reasons of record. Applicants traverse the rejection on the grounds that the specification teaches the skilled artisan how to make and use an antigen presenting vesicle comprising an MHC Class I protein, and specifically, that the instant specification provides guidance on how to isolate exosomes from antigen presenting cells and demonstrates how to use them to stimulate T cells. However, the examiner notes that said guidance regarding the making and using of said exosomes is disclosed in the context of class II only, not in the context of Class I. As repeated from the previous final rejection mailed 1-17-01, the examiner also agrees that the instant specification have described methods of differential centrifugation and isolation of subcellular fractions over sucrose gradients, but the examiner notes that the examples of an antigen presenting vesicle in the instant specification asserted by applicant all refer to the isolation of MIIC and exosomes. In view of the virtual absence of guidance from the instant specification of which vesicles contain class I proteins, and in view of the lack of sufficient guidance in the instant specification regarding how to make and use said vesicles comprising class I proteins, and in view of the lack of predictability concerning MHC Class I expression on exosomes as demonstrated by the post-filing date Zitvogel reference, and in view of the absence of a working definition of "vesicle" in the instant specification, the examiner maintains it would require an undue amount of experimentation on the part of one skilled in the art to make and use the claimed antigen presenting vesicle comprising a MHC Class I protein for the asserted utilities.
3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Art Unit 1644

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner,
Group 1640, Technology Center 1600
May 3, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182